

## **REMARKS**

Claims 36 - 51 remain pending in this application. Claims 36, 37, 44 and 49 - 51 have been amended to more particularly point out and distinctly claim the subject matter of the invention. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 36 - 38, 40-44 and 46 - 48 stand rejected under 35 U.S.C. § 102(e) as anticipated by Kuramoto (U.S. Patent No. 5,395,030). The Examiner stated in support of the rejection that Kuramoto shows an endoscopic stapler having a capsule with a stapling mechanism and a cutter that may be inserted into the large intestine through the anus. The Examiner also stated that Kuramoto discloses an endoscope that is placed inside the capsule and extends through the shaft to the operating handle, which also includes grasping forceps that pull the tissue into the location between the stapler and the anvil.

Claim 36 recites a resection apparatus comprising “an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly” in combination with “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle” and “*a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone, wherein the suturing assembly fastens abutting portions of the grasped fold of tissue.*”

In contrast, Kuramoto only discloses grasping forceps that manipulate and hold only the tip of an anvil shaft. (col. 17, lines 39-41). After the grasping forceps are inserted into the organ,

they are “pulled into the housing of the second unit, drawing the anvil shaft into the hole as shown in Fig. 27.” (col. 18, lines 27-31). Kuramoto never discloses the use of grasping forceps to grasp any tissue, much less to pull tissue into a location between a stapler and an anvil. The Kuramoto device is used only to perform full circular stapling around holes wherein the anvil is placed on a first side of the hole and the stapling mechanism is on the opposite side. The grasping forceps disclosed in Kuramoto then draw the anvil shaft in so that the anvil is positioned properly relative to the stapling mechanism. (See, Fig. 23). Conversely, the method and apparatus according to the present invention provide for grasping tissue so that full thickness portions of the tissue fold over against one another. This fold of tissue is then drawn between the anvil and stapler so that abutting portions of the fold can be stapled together. Consequently, Kuramoto also does not disclose a method of cutting selected tissue after a grasped tissue fold has been fastened.

It is therefore respectfully submitted that claim 36 is not anticipated by Kuramoto and that this rejection should be withdrawn. Because claims 37, 38 and 40 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Claim 44 stands rejected under 35 U.S.C. § 102(e) as anticipated by Kuramoto as applied to claim 36. Claim 44 recites a system for resecting tissue where “*a flexible grasping mechanism extending through the sheath for grasping a full thickness fold of tissue including a portion of tissue selected for resectioning and drawing grasped fold of tissue into a space between the stapling mechanism and the anvil.*” It is respectfully submitted that claim 44 is allowable for the same reasons stated above in regard to claim 36. Because claims 46 - 48 depend from and, therefore, include all of the limitations of claim 44, it is respectfully submitted that these claims are also allowable.

Claims 36-51 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta (U.S. Patent No. 5,389,098) in view of Sauer (U.S. Patent No. 5,562,694) and Kessel (DE Publication No.

4,006,673). The Examiner stated in support of the rejection that Tsuruta shows a stapling assembly substantially as claimed except for the grasper for drawing tissue into the cutting zone and an internal endoscope. The Examiner further stated that Sauer shows a grasper as claimed and that it would have been obvious to have combined the stapling assembly of Tsuruta with the grasper of Sauer to achieve the claimed invention. Furthermore, the Examiner stated that Kessel discloses forceps with an internal endoscope.

Claim 36 has recites “*a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle.*” Unlike the apparatus of claim 36, Tsuruta shows various rigid surgical instruments which are inserted into body cavities. (Col. 2, lines 44-46). It is respectfully submitted that no such flexible member is shown or suggested by Tsuruta.

Although the Examiner stated that Tsuruta discloses a flexible endoscopic stapler. (col. 34, lines 6-15), Tsuruta merely states that “the insertion section of the stapler can be either rigid or flexible” without disclosing any further details of the construction of the device. (col. 34, lines 6-7). A simple statement that an endoscope may be either flexible or rigid is insufficient disclosure to enable one of skill in the art to make such a device operable and flexible. For example, Tsuruta does not disclose the flexible support structure and the mechanisms involved in transmitting manipulations by the user of the stapler from the control handle to the stapler along a flexible endoscope. It is respectfully submitted that, since Tsuruta fails to properly disclose the use of a flexible endoscope, this reference is insufficient to support the rejection.

Similarly, Sauer shows a rigid instrument which is not coupleable to a flexible endoscope and which includes no capsule which is locatable entirely within a body cavity. Although Sauer describes the device as useful in endoscopic surgical procedures, it is clear that the device is not intended for use with a flexible endoscope. Specifically, Sauer states that endoscopic procedures involve “incising through body walls for examining, viewing and/or operating on various bodily

organs or structures” with a trocar being employed to create the incision and tubes being inserted through the incision and left in place in the abdominal wall so that tools may be inserted therethrough. (Col. 1, lines 17-24). Thus, the elongated body portion 14 is not flexible as that term is used in this application and includes no “flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle,” as recited in claim 36.

The Examiner cites Kessel since it discloses forceps with an internal endoscope. That reference, however, does not disclose the use of a flexible endoscope, hence it cannot cure the deficiency of Tsuruta and Sauer.

For these reasons, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either show or suggest an apparatus for resecting tissue within a body lumen, comprising “an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly” in combination with “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle” as recited in claim 36. Furthermore, all of these references are specifically directed to rigid devices for use with open surgery and therefore teach away from the a device for use with a flexible endoscope.

It is therefore respectfully submitted that claim 36 is not obvious over Tsuruta , Sauer, and Kessel either taken alone or in combination and that this rejection should be withdrawn. Because claims 37 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Claim 44 recites “*an operating head including a coupling structure for selectively coupling to the endoscope*, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained, wherein the anvil and the stapling mechanism are permanently coupled to one another,” in combination with “*a flexible grasping mechanism extending through the sheath for drawing tissue into a space between the stapling mechanism and the anvil.*”

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either shows or suggests a system including “*a flexible endoscope*” and “*an operating head including a coupling structure for selectively coupling to the endoscope*,” as recited in claim 44.

Therefore, it is respectfully submitted that claim 44 is not rendered obvious by Tsuruta, Sauer and Bessler either taken alone or in combination and this rejection should be withdrawn. Because claims 45 - 48 depend from and include all of the limitations of claim 44, it is submitted that these claims are also allowable.

Claim 49 recites a method for resecting tissue from within a body lumen, comprising the steps of “*inserting an operating head coupled to a flexible endoscope into a body lumen via a naturally occurring body orifice*, wherein the operating head includes an anvil and a stapling mechanism” and “*advancing the operating head over the endoscope within the body lumen to a desired position relative to a selected portion of tissue to be resected, wherein, when in the desired position, the entire operating head is located within the body lumen* with the flexible endoscope bending to substantially conform to an unstressed configuration of the body lumen.”

As stated above in regard to the rejections of claims 36 and 44, it is respectfully submitted

that the rigidity of the Tsuruta, Sauer, and Kessel devices makes it wholly unsuitable for practicing the claimed method. Specifically, whether or not the Sauer device were coupled to a flexible endoscope as suggested by the Examiner, the rigidity of the device would make it impossible to insert the device into a body lumen via a naturally occurring body orifice to a point where an operating head of the device is entirely received within the body lumen. It is respectfully submitted that Kessler suggests nothing to cure this defect and that neither reference supplies motivation to one of skill in the art to make the proposed combination.

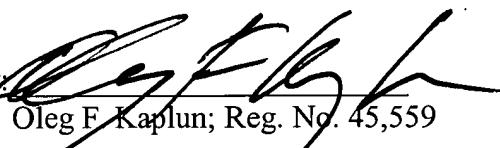
It is therefore respectfully submitted that amended claim 49 is not rendered obvious by Tsuruta, Sauer and Kessler whether taken alone or in combination and that this rejection should be withdrawn. Therefore, it is respectfully submitted that claim 49 is not rendered obvious by Tsuruta, Sauer and Bessler either taken alone or in combination and this rejection should be withdrawn. Because claims 50 and 51 depend from and include all of the limitations of claim 49, it is submitted that these claims are also allowable.

It is respectfully submitted that all of the presently pending claims are allowable and that the present application is in condition for allowance. Therefore, a prompt and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: *Aug. 29, 2003*

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